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| APPLICATION NO.      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|---------------------|------------------|
| 10/589,863           | 08/17/2006  | Claude Dal Farra     | 0591-1010           | 9928             |
| 466                  | 7590        | 10/30/2008           | EXAMINER            |                  |
| YOUNG & THOMPSON     |             |                      | HA, JULIE           |                  |
| 209 Madison Street   |             |                      | ART UNIT            |                  |
| Suite 500            |             |                      | PAPER NUMBER        |                  |
| ALEXANDRIA, VA 22314 |             |                      | 1654                |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/589,863 | <b>Applicant(s)</b><br>DAL FARRA ET AL. |  |
|                              | <b>Examiner</b><br>JULIE HA          | <b>Art Unit</b><br>1654                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-30 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 15-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 15-27, drawn to a composition and a cosmetic and/or dermatological and/or pharmaceutical comprising protein of the uncoupling protein (UCP) family, or protein fragment of the UCP family, as an active agent.

Group 2, claim(s) 28-30, drawn to a method of reducing, eliminating, treating and/or preventing excess subcutaneous fat, cellulite, or orange-peel skin, comprising administering to the skin of a subject an effective amount of a composition comprising protein of the UCP family or fragment thereof.

2. The inventions listed as Groups 1-2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature, a composition comprising UCP family protein or fragment thereof is known in the art. Ni et al (US 2003/0036646 A1, published Feb 20, 2003) teaches human uncoupling polypeptides, and the methods of diagnosing and treating disorders related to these human uncoupling polypeptides (see abstract). Ni teaches the peptide sequences PLDVVKVRLQ (see SEQ ID NO: 38) and PLEVVKTRLQ (see SEQ ID NO: 45) that meet the limitation of instant claim 17. Furthermore, Ni teaches that the polypeptide can be used in treatment of many different diseases, and lists cellulitis as one of skin diseases that can be treated (see paragraph [0701]). Therefore, unity of invention is broken. Additionally, regarding the method claims the MPEP states the following: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim

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referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, a claim to one part referring to another cooperating part, for example, "plug for cooperation with the socket of Claim 1 ..." is not a dependent claim (see MPEP 1850). Therefore, the method claims are in a different category: method of using the products. Since the method claims are dependent claims, these claims lack unity of invention.

3. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

5. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

6. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.**

***Election of Species***

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different UCP protein or fragment thereof: for example, from claim 18;

Different cosmetically or pharmaceutically acceptable solvents: from claim 22;

Different cosmetic or pharmaceutical vector: from claim 23;

Different disorders: cellulite, orange-peel skin or subcutaneous fat;

Different formulations: from claim 27.

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The claims are deemed to correspond to the species listed above in the following manner:

Claims 18-19, 22-23 and 27.

The following claim(s) are generic: Claims 15-17, 20-21, 24-26 and 28-30.

11. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different peptide sequences are patentably independent and distinct due to different amino acid content, therefore, leading to different structure. For example, the sequence PLDVVKVRLQ is different from PTEVAKVRFQ. Further, search for one would not necessarily lead to the other. Different cosmetically or pharmaceutically acceptable solvents are patentably independent and distinct because of their different structures. For example, water has the chemical formula  $H_2O$ , and propylene glycol has the chemical formula  $C_3H_8O_2$ . Further, search for one would not necessarily lead to the other. Different cosmetic or pharmaceutical vectors are patentably independent and distinct due to their different structures. For example, liposome has the structure of micelles; talc has the chemical formula  $Mg_3Si_4O_{10}(OH)_2$ . Further, search for one would not necessarily lead to the other. Different disorders are patentably independent and distinct due to their symptoms are mechanisms. Different formulations are patentably independent and distinct due to the different components involved in the formulation. For example, oil solutions would involve some type of oil solution, and powders would require a dry form of the composition. Further, search for one would not necessarily lead to the other.

12. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

13. If Group I is elected, Applicant is required to elect a single disclosed species of peptide sequence, a single disclosed species of cosmetically or pharmaceutically acceptable solvent and/or vector, and the type of disorder to be treated. Applicant is further required to elect a single disclosed species of the formulation which the compound is formulated in. For example, Applicant elects SEQ ID NO: 1 for peptide sequence, water as the solvent and in the form of a hydro-alcoholic formulation. The composition is for treatment of cellulite. If Group II is elected, Applicant is required to

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elect a single disclosed species of peptide sequence and the type of disorder to be treated. Applicant elects SEQ ID NO: 8 for peptide, and excess subcutaneous fat for the disorder.

14. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

**15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.**

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. H./  
Examiner, Art Unit 1654

/Anish Gupta/  
Primary Examiner, Art Unit 1654